iRhythm

510(k) PREMARKET NOTIFICATION

JUL 21 2009

Executive Summary

1 INTRODUCTION

The Zio ECG Utilization Service System (ZEUS System) is an electrocardiogram (ECG) processing and analysis system designed to handle continuously recorded single lead ECG data It downloads stores analyzes and sorts the ECG data to generate a report of the findings contained within the data thereby enabling the provision of a complete ECG processing and analysis service

The ZEUS System is substantially equivalent to two predicate systems both of which have similar intended uses The scope of functionality of the ZEUS system is encompassed by a combination of the two predicate systems

Automated ECG analysis performance was quantified for any claimed analysis metrics The resulting statistics demonstrate sensitivity and positive predictivity levels which satisfy requirements and minimize safety or efficacy concerns

2 BACKGROUND

The ZEUS System is intended to be used with the Zio family of ECG monitoring devices The Zio devices enable continuous ambulatory ECG data collection over a span of up to 14 days This long recording period increases the likelihood that any transient arrhythmias a patient may be experiencing will be captured Despite the clinical usefulness of recording ECG data for up to 14 days analysis systems currently available on the market are either unable to process recordings of this length or the intensive level of human effort required to do so makes it impractical This often results in the need for patients to receive multiple monitoring tests which results in higher costs and a less than optimal patient experience

To provide our customers with a complete suite of products resulting in a simplified experience with improved diagnostic function at lower cost it was necessary to design a system that was capable of analyzing up to 14 days of continuously recorded single-lead ECG data The ZEUS System meets that requirement and enables iRhythm Technologies Inc (iRhythm) to provide a complete ECG processing and analysis service to our customers

3 INTENDED USE

The Zio ECG Analysis System is intended for use by qualified medical professionals for assessment of a patient s recorded ambulatory ECG data The system is intended to be marketed as a service that downloads and analyzes up to 14 days of ECG data Analysis metrics are provided in a report which is available for clinician review and printing The reported ECG metrics include single-lead analysis on a beat by beat basis heart rate measurement and rhythm analysis The report does not contain diagnostic interpretation the reported analysis is provided for review by the intended user to render a diagnosis based on clinical judgment and experience

4 DEVICE DESCRIPTION

The ZEUS System is a software system designed to be used internally at iRhythm to provide a complete ECG processing and analysis service It includes software that enables ECG data download automated ECG analysis automated report generation and report delivery

via a website It is capable of automated ECG analysis on continuously recorded single-lead ECG data up to 14 days in duration

5 SUBSTANTIAL EQUIVALENCE

Legally marketed predicate systems

510(k) Number	Product	Manufacturer
K042463	Ambulatory ECG Analysis System	Rozinn Electronics Inc
K062282	Automated ECG Analysis and Interpretation Software	Monebo Technologies Inc

The ZEUS System is substantially equivalent to the Rozinn Holter Plus System and the Monebo Analysis Software Library The Rozinn Holter Plus System is an end to end ECG processing system implemented in the form of software used by the clinic to download ECG data and process a complete report output It enables human-assisted ECG analysis The Monebo Software Library is a software library that enables automated ECG analysis of beats runs rhythms and heart rate

The ZEUS System combines the end to-end ECG processing capabilities of the Rozinn system with the automated ECG analysis functionality of the Monebo software library

The table below summarizes key similarities of the ZEUS system with the predicate systems

	ZEUS System	Rozinn Holter Plus	Monebo SW Library
Intended Use	Recorded ECG data processing and analysis	Recorded ECG data processing and analysis	Recorded ECG data analysis
System capabilities	ECG data download analysis and reporting	ECG data download analysis and reporting	ECG data analysis only
Data Analysis	Automated beat run rhythm and heart rate analysis	Preliminary automated analysis of beat run and heart rate analysis with human intervention required to identify certain rhythms	Automated beat run rhythm and heart rate analysis

Extensive performance testing was conducted on the automated analysis algorithm portions of the ZEUS system to ensure that automated performance was substantially equivalent to the Monebo automated analysis metrics Equivalence with the Rozinn Holter Plus System was demonstrated through a study that compared analysis reports for a 48 hour continuous ECG recording

6 COMPLIANCE TESTING

Compliance testing was performed to two industry standards

- ANSI/AAMI EC57
- IEC60601-2 51

These two standards define the required testing and reporting methods used to assess the performance of an automated analysis algorithm All metrics reported in this submission were obtained using the methods required by these two standards Further details on compliance to these standards can be found in Section 10 of this submission

These standards do not provide minimum performance requirements Minimum performance standards were developed internally at iRhythm in consultation with our clinical team and are documented in Section 13 of this submission Section 17 describes in greater detail the methods and test results used to verify that the automated analysis algorithm portions of the ZEUS system meet the requirements when tested in compliance with the industry standards above

7 PRECAUTIONS

The ZEUS system is not designed for analysis of ECG recordings from pediatric patients or those patients with paced beats

8 CONCLUSION

Based on thorough verification testing quantification of algorithmic performance and substantial equivalence comparison with predicate systems it is our determination that the ZEUS system is substantially equivalent to the legally marketed predicates

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2009

Mr. Michael Righter
Regulatory and Quality Assurance Engineer
iRhythm Technologies, Inc.
650 Townsend Street, Suite 380
San Francisco, CA 94103

Re: K091075
Trade/Device Name: ZEUS System Model S100
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Codes: DQK
Dated: July 13, 2009
Received: July 15, 2009

Dear Mr. Righter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

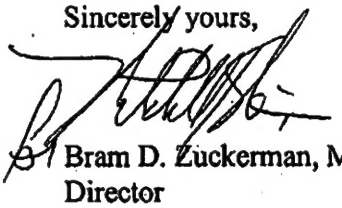
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

iRhythm

INDICATIONS FOR USE STATEMENT

510(k) Number: K091075

Device Names: ZEUS System

Indications for Use:

The ZEUS System is intended for use by qualified medical professionals for assessment of a patient's recorded ambulatory ECG data. The system is intended to be marketed as a service that downloads and analyzes up to 14 days of ECG data. Analysis metrics are provided in a report which is available for clinician review and printing. The reported ECG metrics include single-lead analysis on a beat by beat basis, heart rate measurement and rhythm analysis. The report does not contain diagnostic interpretation; the reported analysis is provided for review by the intended user to render a diagnosis based on clinical judgment and experience.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman

(Division Sign-Off) 7/21/09
Division of Cardiovascular Devices
510(k) Number K091075